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Group Art Unit 3738/Examiner P. Prebilic

**Firm:** U.S. Patent & Trademark Office

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**Subject:** U.S. Patent Application No. 09/991,247  
Gary K. Michelson, M.D.  
Filed: November 15, 2001  
RATCHETED BONE DOWEL  
Attorney Docket No. 101.0083-00000  
Customer No. 22882  
Confirmation No.: 4911

**FROM:**

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PATENT  
Attorney Docket No. 101.0083-00000  
Customer No. 22882

APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: ) Confirmation No.: 4911  
Gary K. Michelson, M.D. )  
Serial No.: 09/991,247 ) Group Art Unit: 3738  
Filed: November 15, 2001 ) Examiner: P. Prebilic  
For: RATCHETED BONE DOWEL )

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REPLY BRIEF

In reply to the Examiner's Answer, Appellant submits the following remarks for consideration by the Board of Patent Appeals and Interferences.

**I. The Supplemental Motivation Provided in the Examiner's Answer is Unsupportable.**

In the Final Rejection dated January 30, 2004, the Examiner contended that it would have been obvious to combine the teachings of U.S. Patent No. 5,860,973 to Michelson ("Michelson '973") and U.S. Patent No. 6,294,187 to Boyce et al. ("Boyce") "for the same reasons that Boyce does the same; see column 1, line 56 to column 2, line 4 of Boyce." (Final Office Action, page 4, paragraph 1). In the Appeal Brief, Appellant presented arguments as to why the requisite motivation to support the combination was lacking. (See Appeal Brief, pages 5-7). These arguments are incorporated by reference herein. In the Examiner's Answer, the Examiner supplemented his motivation to include that it would have been obvious to make the Michelson implant out of the cortical bone/bioresorbable material composite of Boyce "as a binder to the hydroxylapatite [sic] particles of Michelson." (Examiner's Answer, paragraph bridging pages 3-4).

Reply Brief 1-4-05.doc

Appellant submits that the supplemental motivation provided by the Examiner is unsupportable because it would render the implant taught by Michelson '973 unsuitable for its intended purpose of functioning as a spinal fusion implant. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose" (May 2004)).

Michelson '973 states that "the spinal fusion implant 100 itself is made of material appropriate for human implantation such as...hydroxyapatite." (Michelson '973, col. 5, line 66 to col. 6, line 3). Michelson does not disclose an embodiment of an implant formed of hydroxyapatite particles as asserted by the Examiner. Boyce teaches bone particle osteoimplants that can be formed by combining bone particles "with one or more biocompatible components such as...fillers." (Boyce, col. 7, lines 55-57). One of the fillers listed by Boyce includes hydroxyapatite. (Boyce, col. 8, lines 53-54). Once the bone particle composition is mixed together, it is then compressed and molded into a suitable shape for use as an osteoimplant. (Boyce, col. 11, lines 11-14, 39-41, and 65-66). In order to provide a combination of hydroxyapatite particles and binder material as proposed by the Examiner, the spinal fusion implant made of hydroxyapatite as taught by Michelson '973 would have to be turned into hydroxyapatite particles and subsequently combined with binder material to form an osteoimplant such as taught by Boyce. The resulting implant would be unsuitable for the intended purpose of providing spinal fusion between adjacent vertebrae through the implant. For example, chamber 214 of the implant of Fig. 8 of Michelson '973 would not exist if the implant were formed according to the teachings of Boyce. (See MPEP § 2143.01, "The Proposed Modification Cannot Change the Principle of Operation of a Reference" (May 2004)). Accordingly, Appellant respectfully submits that the Examiner's supplemental motivation provided in the Examiner's Answer is unsupportable.

**II. Reply to the Examiner's "Response to Argument" section of the Examiner's Answer.**

At the end of the Examiner's Answer, the Examiner responded to three points made in the course of Appellant's Appeal Brief. Appellant respectfully submits the following remarks in reply to the Examiner's response.

A. The Examiner's Contention that both Michelson '973 and Boyce Disclose Using "Bone Graft Material in the Form of Hydroxyapatite" Does Not Provide the Requisite Motivation to Combine the References.

In the Examiner's Answer, the Examiner contended that Appellant's argument was "wholly unpersuasive" because "both Michelson '973 and Boyce '187 disclose using bone graft material in the form of hydroxylapatite [sic]." (Examiner's Answer, page 6, paragraph 2). Appellant submits that just because both references disclose the use of hydroxyapatite, that use does not provide the necessary nexus needed to support a motivation to combine the references. Appellant submits that the arguments presented in the Appeal Brief remain applicable in view of the Examiner's remarks set forth in the Examiner's Answer.

B. The Examiner's Contention That There is No Support For the Implants Taught by Michelson '973 Being Stronger Than Bone Grafts or Bone Composite is Unpersuasive.

In the Examiner's Answer, the Examiner contends that "Appellant provides no support for this allegation that the implants of Michelson '973 are stronger than either bone grafts of [sic] the bone composite of Boyce." (Examiner's Answer, page 6, paragraph 3). Michelson '973 discloses that "spinal fusion implant 100 itself is made of a material appropriate for human implantation such as titanium." (Michelson '973, col. 5, lines 66-67). It is well known to those of ordinary skill in the art that titanium is stronger than bone. Accordingly, Appellant's point that "[t]here would be no need to make these implants of Michelson '973 stronger as they did not suffer the load bearing problems that Boyce '187 was trying to solve" because "these implants of Michelson '973 are already stronger than either bone grafts or the bone composite of Boyce '187" remains valid in the face of the Examiner's remarks set forth in the Examiner's Answer. (Appeal Brief, paragraph bridging pages 6-7).

Appellant respectfully disagrees with the Examiner's contention that "Michelson discloses a wide variety of materials for making the bone graft." (Examiner's Answer, paragraph bridging pages 6-7). In fact, neither Michelson '973 nor Boyce teach making a "bone graft." As expressly defined by Boyce, bone grafts are limited by the size and shape limitations of the bone tissue from which the bone graft originated. (See, Boyce, col. 1, lines 47-50). Michelson teaches spinal fusion implants. (Michelson '973, col. 1,

lines 16-17). Boyce teaches osteoimplants formed from a compressed bone particle composition. (Boyce, col. 2, lines 35-37). The spinal fusion implants of Michelson '973 and the osteoimplants of Boyce are not limited by the size and shape of the bone tissue available or the strength limitation of the bone tissue itself. Thus, Appellant respectfully submits that the Examiner's contention concerning Appellant's remarks addressing the strength of the Michelson '973 implants is unpersuasive.

C. The Examiner's Contention That Michelson '973 and Boyce Are Not Mutually Exclusive is Unpersuasive.

In the Examiner's Answer, the Examiner contended that "Michelson and Boyce are clearly not mutually exclusive because they both disclose using bone graft material (i.e. hydroxylapatite [sic]) and because both disclose making their implants from a wide variety of materials in the same art." (Examiner's Answer, page 7, paragraph 1). The fact that both references mention the use of hydroxyapatite does not make them instantly combinable. As set forth in the Appeal Brief, "one of ordinary skill in the art would not look to combine the teachings of Michelson '973 and Boyce '187 without the benefit of Appellant's teachings in the disclosure of the present application." (Appeal Brief, page 7, paragraph 2). Appellant maintains that Michelson '973 and Boyce are mutually exclusive, particularly because of the methodologies and types of implants described in each patent. For example, Boyce discloses producing a bone particle composition and then compressing the composition into an osteoimplant. (Boyce, col. 11, lines 11-12). This is a completely different process than that used to manufacture the implants of Michelson '973. Accordingly, Appellant submits that the teachings of Michelson '973 and Boyce are mutually exclusive and that the Examiner's rejection was fashioned as a result of improper hindsight.

Appellant respectfully submits that independent claims 1, 29, and 60 are patentable over the art of record and that dependent claims 2, 3, 5-28, 30-59, and 61-88 dependent from one of independent claims 1, 29, and 60 or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: January 4, 2005

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